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Attorney's Office No. 26252

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

BEUME et al.

International Application No. PCT/EP03/01876

Serial No. 10/506,875

International Filing Date: 25 February 2003 (25.02.2003)

Filed: September 3, 2004

For: **PHARMACEUTICAL COMPOSITION OF A PDE 4 OR A PDE 3/4 INHIBITOR  
AND A HISTAMINE RECEPTOR ANTAGONIST**

TRANSMITTAL LETTER

Commissioner of Patents  
P.O. Box 1450  
Alexandria, Va 22313-1450

Sir:

Submitted herewith for filing in the U.S. Patent and Trademark Office is the following:

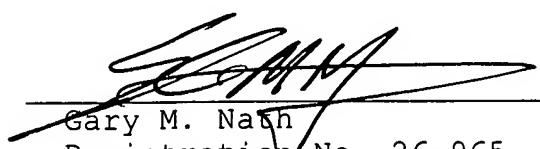
- (1) Transmittal Letter;
- (2) Information Disclosure Statement;
- (3) PTO Form 1449 citing 15 references;
- (4) Copies of 12 references.

The Commissioner is hereby authorized to charge any deficiency or credit any excess to Deposit Account No. 14-0112.

Respectfully submitted,

**NATH & ASSOCIATES PLLC**

By:

  
Gary M. Nath  
Registration No. 26,965  
Sheldon M. McGee  
Registration No. 50,454  
Customer No. 34375

Date: November 2, 2004  
NATH & ASSOCIATES PLLC  
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

An Information Disclosure Statement is submitted herewith pursuant to 37 C.F.R. § 1.97-1.98. Please note the following particulars:

[NOTE: One only of items a, b, c, and d must be checked.]

[ X ] a. The enclosed statement is being filed within three months of the filing date of a national application, or within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 in an international application, or before the mailing date of a first Office Action on the merits, whichever event occurs last.

[ ] b. The enclosed statement is being filed after a first action on the merits but before the mailing date of a final action under 37 C.F.R. § 1.113, or a notice of allowance under 37 C.F.R. § 1.311.

The enclosed statement is accompanied by [check one]:

[ ] i. a certification in part (e) below as specified in 37 C.F.R. § 1.97(e), or

[ ] ii. a check in the amount required by 37 C.F.R. § 1.17(p).

[ ] c. The enclosed statement is being filed after the mailing date of a final action under 37 C.F.R. § 1.113, or a notice of allowance under 37 C.F.R. § 1.311, but before payment of the issue fee.

[ ] Certification report(e) below; and

[ ] a check in the amount as required by § 1.17(p).

[ ] d. The enclosed statement is being filed pursuant to 37 C.F.R. § 1.97(i), for placement in the file.

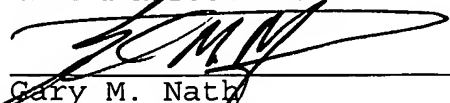
- ☐ e. Certification [Check one] [Certification is required only if box (b)(i) or box (c) is checked]
- ☐ I hereby certify that each item of information contained in the enclosed Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement,
- or
- ☐ I hereby certify that no item of information in the enclosed Information Disclosure Statement herewith was cited in a communication from a foreign patent office in a counterpart foreign application, or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.
- or
- ☐ Appropriate certification is attached.
- ☒ f. If no check is enclosed and a fee is due in connection with this communication or if the check enclosed is insufficient, the Commissioner is authorized to charge any fee or additional fee due in connection with this communication to Deposit Account No. 14-0112.
- ☒ g. Copies of the documents are attached herewith with a completed Form PTO-1449.
- or
- ☒ Copies of the documents are not attached as allowed under CFR 1.98(d)(1)(2). The earlier application is identified as: or Copies of US Patents/Publications not attached as allowed in Official Gazette Aug. 5, 2003/ Vol. 1273, no. 1.

The Examiner is respectfully requested to cite the documents listed on the attached Form PTO-1449 in the next Office Action. In so doing, the Examiner is respectfully requested to initial in the space adjacent to the listing of each document on the Form PTO-1449, and return a copy of the initialed Form PTO-1449 with the next communication to Applicants, to confirm that these documents have been considered by the Examiner and made of record in this application.

If the Examiner has any questions or wishes to discuss this application, kindly telephone the undersigned at the below-listed number.

Respectfully submitted,  
NATH & ASSOCIATES

By: \_\_\_\_\_

  
Gary M. Nath  
Registration No. 26,965  
Sheldon M. McGee  
Registration No. 50,454  
Customer No. 34375

Date: NOVEMBER 2, 2004

<b>FORM PTO-1449</b>  <b>SUPPLEMENTAL INFORMATION DISCLOSURE CITATION</b>				Atty Docket 26252		Serial No. 10/506,875	
				Applicant BEUME et al.			
				Filing Date September 3, 2004		Group Art Unit Not Yet Assigned	
<b>U.S. PATENT DOCUMENTS</b>							
Examiner Initial		Document Number	Issue Date	Name	Class	Sub-Class	Filing Date
	AA	4,400,506	08.23.83	Lal et al.			10.26.81
	AB	5,990,147	11.23.99	Aslanian			11.05.98
	AC	5,962,464	10.05.99	Handley et al.			07.06.98
<b>FOREIGN PATENT DOCUMENTS</b>							
		Document Number	Date	Country	Class	Sub-Class	Translation
	AD	EP 1 005 865 A1	07.06.00	EP			N/A
	AE	WO 01/30777 A1	3.05.01	WIPO			N/A
	AF	WO 99/32125	1.07.99	WIPO			N/A
	AG	WO 03/000289 A1	03.01.03	WIPO			N/A
<b>OTHER (Including Author, Title, Date, Pertinent Pages, etc.)</b>							
	AH		Marx, D. et al. "The <i>n vivo</i> Activity of AWD 12-281, a Potent PDE4 Inhibitor for the Treatment of Allergic Asthma", <u>J. Allergy Clin. Immunol.</u> , vol.103(1) p.S127, 1999.				
	AI		Bundschuh, D. et al. "In Vivo Efficacy in Airway Disease Models of Roflumilast, a Novel Orally Active PDE4 Inhibitor", <u>The Journal of Pharmacology and Experimental Therapeutics</u> , vol.297(1), pp.280-290, 2001.				
	AJ		Hatzelmann, A. et al. "Anti-Inflammatory and Immunomodulatory Potential of the Novel PDE4 Inhibitor Roflumilast in Vitro", <u>The Journal of Pharmacology and Experimental Therapeutics</u> , vol.297(1) pp.267-279, 2001.				
	AK		Ashton, M.J. et al. "Selective Type IV Phosphodiesterase Inhibitors as Antiasthmatic Agents. The Syntheses and Biological Activities of 3-(Cyclopentyloxy)-4-methoxybenzamides and Analogues", <u>J.Med.Chem.</u> , vol.37(11) pp.1696-1703, 1994.				
	AL		Holden, C.A. et al. "Histamine induced elevation of cyclic AMP phosphodiesterase activity in human monocytes", <u>Agents and Actions</u> , vol.22 pp.36-42, 1987.				
	AM		Lieberman, P. "American Academy of Asthma, Allergy and Immunology-55 <sup>th</sup> Annual Meeting", <u>IDrugs</u> , vol.2(5) pp.405-409, 1999.				
	AN		Phillips, G.D. et al. "The effect of histamine-H1 receptor antagonism with terfenadine on concentration-related AMP-induced bronchoconstriction in asthma", <u>Clinical and Experimental Allergy</u> , vol.19 pp.405-409, 1989.				
	AO		Andri, L. et al. "Combined treatment of allergic rhinitis with terfenadine and nimesulide, a non-steroidal antiinflammatory drug", <u>Allergie et Immunologie</u> , vol.24(8) pp.313-319, 1992.				
Examiner				Date Considered			
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP ' 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.							